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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,690	10/08/2003	Vincent Chau	MPI97-057P1RCPICN1M	7707

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MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,690

Applicant(s)

CHAU, VINCENT

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31,34,36-38,56 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) 34,36-38 and 59-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/11/06, 10/08/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

1. Claims 30, 31, 34, 36, 37, 38, 56, 59-64 are pending in the instant application in view of the applicants' amendment dated 04/11/2006.

2. Applicant's election with traverse of Group X (claims 30, 31, and 56) in the reply filed on 04/11/2006 is acknowledged. The examiner agrees with applicant's arguments filed 04/11/2006 that Group X is related to Groups XII, XIII, and XV (claims 33, 34, and 36-38). The examiner acknowledges that applicant has withdrawn claims 33, 34, and 36-38 and is submitting new claims 60-64.

Group X and the invention of new claims 60-64 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the protein in a process to make antibodies to the protein. As stated in the previous Office Action where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

In regard to new claim 59 which is directed toward dominant negative mutants of a NEDD8 conjugating enzyme 1, the invention of Group X and invention of claim 59 are patentably distinct products because each of the products are independent chemical entities that require different literature searches. The protein of Group X and the protein of claim 59 are distinct molecules with different biological functions that require different literature searches.

A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes is proper.

The requirement is still deemed proper and is therefore made FINAL. New claims 59-64 have been entered but are withdrawn from consideration as being drawn to a non-elected invention.

3. Claims 30, 31, and 56 are under consideration in this Office Action.

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4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. The disclosure is objected to because of the following informality: in the preliminary amendment dated 10/8/2003, there is no statement that indicates that application Serial No. 09/216,430 is now US Patent 6,734,283. Appropriate correction is required.

6. Claims 30, 31, and 56 are objected to because of the following informalities: the claims as written recite the abbreviations "NEDD8" and "NCE1" without defining the terms in the claims. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 30 and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified "Neural precursor cell-Expressed Developmentally Down regulated" (NEDD8)-conjugating enzyme comprising the amino acid sequence of SEQ ID NO: 4; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any NEDD8-conjugating enzyme selected from the group consisting of a protein at least 95% identical to SEQ ID NO: 4 and a protein encoded by an expression element comprising a nucleic acid sequence at least 95% identical to SEQ ID NO: 3 wherein the protein comprises amino acid residue 111 of SEQ ID NO: 4.

The specification provides guidance and working examples for a NEDD8-conjugating

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enzyme consisting of the amino acid sequence of SEQ ID NO: 4 which is encoded by the polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 3. However, the specification does not provide guidance, prediction, and working examples for making any protein at least at least 95% identical to SEQ ID NO: 4 and any protein encoded by an expression element comprising a nucleic acid sequence at least 95% identical to SEQ ID NO: 3 wherein the protein comprises amino acid residue 111 of SEQ ID NO: 4.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any protein having at least 95% identity to SEQ ID NO: 4 or any protein encoded by any expression element comprising a nucleic acid sequence at least 95% identical to SEQ ID NO: 3 wherein the protein comprises amino acid residue 111 of SEQ ID NO: 4. Alternatively, trial and error experimentation must then be performed to search and screen for specific amino acid residues in SEQ ID NO: 4 to change (e.g., amino acid deletion, insertion, substitution, and combinations thereof) or specific nucleotide to change in SEQ ID NO: 3 (e.g., nucleotide deletion, insertion, substitution, and combinations thereof) which will not result in inactivation of the claimed enzyme. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid residues in SEQ ID NO: 4 and specific nucleotides in SEQ ID NO: 3 to change which does not affect enzyme activity. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation. Claim 56 is also included in the rejection because it does not correct the defect of claim 30.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 30, 31, and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by Osaka et al. (Genes Dev. 1998 Aug 1;12(15):2263-8; and Accession P61081).

The priority date for the claimed invention is 08/12/1998 since the nonprovisional

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application Serial No. 60/096,525 (filed on 08/12/1998) first discloses the amino acid sequence of SEQ ID NO: 4 of the NEDD8-conjugating enzyme 1 and the polynucleotide of SEQ ID NO: 3 encoding said NEDD8-conjugating enzyme 1.

Osaka et al. teach a purified NEDD8-conjugating enzyme which has an amino acid sequence that is 100% identical to SEQ ID NO: 4, and a polynucleotide encoding said NEDD8-conjugating enzyme which is 100% identical to SEQ ID NO: 3 which encodes SEQ ID NO: 4 (see enclosed alignments)

Osaka et al. also teach purified complexes of said NEDD8-conjugating enzyme and NEDD8 (see Genes Dev. 1998, section titled *Identification of a NEDD*-conjugating enzyme* on pp. 2264-2265 and Figure 3B).

Thus, the reference teachings anticipate each of the claims.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER